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Nos. 80-157, 80-158,
80-170, 80-172
IN THE

Supreme Court of the United States

October Term, 1980

E. R. SQUIBB & SONS, INC.,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

THE UPJOHN COMPANY,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

REXALL DRUG COMPANY and ELI LILLY AND COMPANY,
Petitioners,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

ABBOTT LABORATORIES,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

BRIEF IN OPPOSITION TO PETITIONS FOR WRITS OF CERTIORARI.

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QUESTIONS PRESENTED.

This case presents the following federal constitutional questions:

1. Whether Petitioners waived their rights to assert certain constitutional issues by failing to properly raise the issues in the courts below.

2. Whether a judicial modification of the doctrine of *Summers v. Tice*, 33 Cal.2d 80 (1948), which apportions damages in proportion to market share, violates the Due Process and Equal Protection Clauses of the Fourteenth Amendment.

3. Whether a judicial modification of the doctrine of *Summers v. Tice*, which apportions damages in proportion to market share, is prohibited under the Supremacy Clause or is invalid as an impermissible burden on interstate commerce.

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STATEMENT OF CASE.

A. Introduction.

In *Sindell*, the California Supreme Court modified the doctrine of the celebrated case of *Summers v. Tice*, 33 Cal.2d 80 (1948). The Court's decision was a response to needs which arise when ". . . advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer." 26 Cal.3d at 610. Faced with a problem which did not fit neatly within any existing judicial doctrine, the California Supreme Court recognized that it could "either . . . adhere to prior doctrine, denying recovery to those injured by such products, or . . . fashion remedies to meet these changing needs." 26 Cal.3d at 610. Applying the principle set forth in Justice Traynor's concurring opinion in *Escola v. Coca Cola Bottling Co.*, 24 Cal.2d 453, 467-468 (1944),[1] the Court chose the latter course of action.

B. The Problem before the California Supreme Court.

The portion of the California Supreme Court's majority opinion which is reproduced in Appendix A provides a good summary of the problem before that court.

C. The Decision of the California Supreme Court.

As stated above, the California Supreme Court modified the doctrine of *Summers v. Tice* to provide a remedy for injuries to DES daughters who cannot identify the manufacturer of the drug that their mothers ingested. Consistent with the doctrine of *Summers v. Tice*, the California Supreme Court fashioned a remedy which shifts the burden of proof for causation to the defendants. Upon a showing that the plaintiff has "joined in the action the manufacturers of a substantial share of the DES which her mother might

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[1]The California Supreme Court, in its majority opinion, stated:

> "Just as Justice Traynor in his landmark concurring opinion in *Escola v. Coca Cola Bottling Co.*, (1944) 24 Cal.2d 453, 467-468, recognized that in an era of mass production and complex marketing methods the traditional standard of negligence was insufficient to govern the obligations of manufacturer to consumer, so should we acknowledge that some adaption of the rules of causation and liability may be appropriate in these recurring circumstances." 26 Cal.3d at 610.

have taken," the burden of proof as to who actually manufactured the injury-producing drug shifts to the defendants. Any defendants who cannot demonstrate that they could not have made the product ingested by plaintiff's mother are held liable for the cost of plaintiff's injuries. Unlike the doctrine of *Summers v. Tice*, the *Sindell* decision does not hold such defendants jointly and severally liable for the court's judgment. Deciding that joint and several liability would be too harsh in this context, the California Supreme Court held that "[e]ach defendant will be liable for the proportion of the judgment represented by its share of that market . . ." The Court decided that by apportioning liability for damages by market share, each manufacturer's liability would, ultimately, be "approximately equivalent to the damages caused by the DES that it manufactured." 26 Cal.3d at 617.

Following this decision, Petitioners asserted constitutional arguments in petitions for rehearing. The California Supreme Court denied these petitions without opinion.

REASONS FOR DENYING WRIT.

I.

THE UNITED STATES SUPREME COURT DOES NOT HAVE JURISDICTION TO HEAR PETITIONERS' COMMERCE CLAUSE AND SUPREMACY CLAUSE CLAIMS BECAUSE THESE CLAIMS WERE NOT PROPERLY RAISED AND PRESERVED IN THE STATE COURTS BELOW.

28 U.S.C., §1257(3) provides:

> "Final judgments or decrees rendered by the highest court of a State in which a decision could be had, may be reviewed by the Supreme Court as follows: . . .
>
> (3) By writ of certiorari, . . . where any title, right, privilege or immunity is specially set up or claimed under the Constitution, . . ."

Petitioners claim that the *Sindell* decision violates the Equal Protection and Due Process Clauses[2] and is preempted by Article I, Section 8, Clause 3, and Article VI, Clause 2 of the Constitution of the United States.

It has long been established that the United States Supreme Court does not have jurisdiction to hear a case unless a "substantial" federal question has been raised and decided in the state court below. *Cardinale v. Louisiana*, 394 U.S. 437, 438 (1969).[3] Generally, the federal questions must be raised precisely as required by state practice. When the highest state court does not pass on the federal question, any failure to follow state practice will result in a denial of review. *In Re Lamkin*, 355 U.S. 59 (1957).

As a general rule, California requires that a constitutional question must be raised at the earliest opportunity or it will be deemed waived. *Hershey v. Reclamation Dist.*, 200 Cal. 550 (1927); *Preston v. Municipal Court*, 188 Cal.App. 2d

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[2]For purposes of this discussion, we concede that this Court has jurisdiction to hear the Equal Protection and Due Process claims. Although the Due Process and Equal Protection claims were not properly raised by Petitioners, the California Supreme Court's discussion of these claims gives this Court jurisdiction to hear them.

[3]"The rule that in cases coming from state courts, this court may review only those issues which were presented to the state court is not discretionary but jurisdictional." *Amalgamated Food Employee Union v. Logan Valley Plaza*, 391 U.S. 308, 344 (1968). [dissenting opinion].

76 (1961).[4] Furthermore, it may be waived directly or indirectly.[5] *Chesney v. Byram*, 15 Cal.2d 460 (1940); *People v. Workham*, 121 Cal.App.2d 533 (1953).

Petitioners raised their Commerce Clause and Supremacy Clause claims for the first time in their petitions for rehearing before the California Supreme Court. Raising a federal question for the first time in a petition for rehearing before a state's highest court is generally insufficient unless that court actually entertains the petition and expressly decides the question. *Radio Station WOW v. Johnson*, 326 U.S. 120, 128 (1945); *Hansen v. Denckla*, 357 U.S. 235, 243-244 (1958).[6] Because the California Supreme Court did not entertain the petitions for rehearing and did not decide the Commerce Clause and Supremacy Clause issues, this Court does not have jurisdiction to hear these claims.

Petitioners claim, however, that the petitions for rehearing before the California Supreme Court were their first opportunity to raise the Commerce Clause and Supremacy Clause issues "because the theory of liability reached by the court was so revolutionary and completely unanticipated."[7] Petitioners' reliance on the doctrine of "surprise" for this proposition is unsupportable. It simply cannot be

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[4]In both situations, the California Supreme Court refused to hear appellants' claims that the relevant statutes were unconstitutional. The Court in both cases stated:

> "A party questioning the constitutionality of a statute or its application must raise the constitutional issue at the earliest opportunity."

[5]Directly by admission or by consent, and indirectly by failure to present a claim. Here, Petitioners indirectly failed to raise their claims.

[6]In order to constitute a reviewable judgment under such circumstances, the order denying the petition for rehearing must be more than a cursory statement that the Petitioners' claims have been considered and denied. There must be language in the order denying the petition for rehearing that the federal question was considered and disposed of on the merits. In other words, the state court must discuss the issue "in such a way that the case could have been brought here had the questions been raised prior to the original disposition." *Radio Station WOW v. Johnson*, 326 U.S. at 128. Because the California Supreme Court denied the petitions for rehearing without opinion, the Commerce Clause and Supremacy Clause claims were not entertained and expressly decided under these rules.

[7]Petitioners Rexall Drug Company and Eli Lilly and Company, Petition at p. 7.

said that the remedy in the *Sindell* case was unanticipated. The *Sindell* remedy was merely an extension of the *Summers* doctrine[8] and, therefore, should have been anticipated.[9] Furthermore, Petitioners should have anticipated any Commerce Clause and Supremacy Clause claims in response to *any* remedy devised by the California Supreme Court in favor of Respondents. (For example, Petitioners claim that the *Sindell* decision is preempted by the Supremacy Clause because it frustrates the federal policy in favor of generic drugs.[10] The same claim, however, could have been made following the Court of Appeal's decision[11] or for that matter, any other decision in favor of Respondents.) And yet, Petitioners failed to raise any Supremacy Clause or Commerce Clause claims when they petitioned for rehearing before the Court of Appeals, or when they appealed the decision of the Court of Appeals to the California Supreme Court. As a result, Petitioners cannot persuasively argue that either the remedy or results of the decision of the California Supreme Court were unanticipated.

Petitioner Squibb also argues that its Commerce Clause and Supremacy Clause arguments were properly raised because Petitioners have shown that this Court has jurisdiction to hear certain other constitutional claims attacking the *Sindell* rule.[12] It is a well-settled rule that the Supreme Court only has jurisdiction to consider the denial of other federal rights flowing from a judgment when the judgment is before this Court under its *appellate* jurisdiction and where the other claims in question can be brought before the Court

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[8]Respondent urged the application of the *Summers v. Tice* doctrine from the beginning of the *Sindell* proceedings. This doctrine was raised at the Superior Court level in respondent's complaint and in points and authorities in opposition to Petitioners' demurrers.

[9]Petitioners surely cannot be understood to suggest that every turn the law takes is unanticipated.

[10]Petitioners Rexall Drug Company and Eli Lilly and Company, Petition at p. 21.

[11]The same is true of the rest of Petitioners' Commerce Clause and Supremacy Clause claims. All these claims could have been made following the Court of Appeal's decision. Petitioners' failure to raise them at that time constitutes waiver.

[12]Petitioner E. R. Squibb & Son, Inc., p. 21. Citing *Flournoy v. Weiner*, 321 U.S. 253, 263 (1944); *Prudential Insurance Co. v. Cheek*, 259 U.S. 530, 547 (1922).

under its certiorari jurisdiction. This Court, in *Cox Broadcasting Corp., et al. v. Cohn,* 420 U.S. 469, 487 (1975) n. 14, explained, "In finding we have *appellate* jurisdiction, we also take jurisdiction over any aspects of the case which would otherwise fall solely within our *certiorari* jurisdiction." [emphasis added]. Petitioner's attempt to apply this rule to *Sindell* is clearly erroneous. As stated above, this doctrine is applicable only when the Supreme Court has *appellate* jurisdiction over at least one issue which is properly before the Court. In this case, the only issues properly before the Court are Petitioners' Due Process and Equal Protection claims. Those claims are before the Court on writ of certiorari. Therefore, this doctrine cannot be used to provide this Court with jurisdiction over Petitioners' Commerce Clause and Supremacy Clause claims.

II.

THE SINDELL DECISION DOES NOT DEPRIVE PETITIONERS OF DUE PROCESS OF LAW.

The Fourteenth Amendment provides that "No state shall . . . deprive any person of life, liberty, or property, without due process of law." This constitutional provision has been interpreted to provide both procedural and substantive safeguards.

A. The Sindell Decision Does Not Deprive Petitioners of Procedural Due Process.

Petitioners argue that the *Sindell* decision creates a rule of evidence relating to causation which deprives them of procedural due process.

Although the due process right to a hearing is generally found to embrace the right to present evidence, a state has considerable power to make or change rules which govern the introduction of evidence at trial to prove a particular issue. *Luria v. United States*, 231 U.S. 9 (1913).

(1) The Sindell Decision Does Not Create a Conclusive Presumption of Causation.

Corpus Juris Secundum, Vol. 31A, Evidence, §115, p. 197, distinguishes between conclusive and rebuttable presumptions as follows:

> "A conclusive presumption is a rule of substantive law, rather than of evidence, while a disputable or rebuttable presumption is a species of evidence that may be accepted or acted upon when there is no other evidence to uphold the contention for which it stands, or one which may be overcome by other evidence. When a statute makes a presumption conclusive, it cannot be rebutted by evidence." [footnotes omitted].

These definitions make it clear that the *Sindell* rule cannot be classified as a conclusive presumption of causation. The *Sindell* rule simply shifts the burden of proof to the defendant drug manufacturers when the plaintiff cannot identify which company manufactured the DES that her mother ingested. Under this rule, each defendant drug manufacturer has the opportunity to demonstrate "that it could not have made the product which caused the plaintiff's injuries."[13] Because each defendant is allowed to introduce such evidence, the *Sindell* decision can, at most, be interpreted as creating a rebuttable presumption of causation.[14]

(2) As Either a Rebuttable Presumption of Causation or an Allocation of the Burden of Proof, the Sindell Decision Does Not Deprive Petitioners of Procedural Due Process.

In civil cases, procedural due process requires that rebuttable presumptions and allocations of the burden of proof

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[13]26 Cal.3d at 612. Petitioners contend that the *Sindell* decision, by eliminating market share data as a means of showing lack of causation, effectively deprives them of *all* evidence that could be used to show they could not have caused plaintiff's injury. This contention ignores ample evidence which can be used to show lack of causation, *e.g.*, evidence showing that (1) defendant did not manufacture DES at time of ingestion, (2) defendant did not sell DES in the state where the drug was ingested, (3) defendant did not sell DES to the pharmacy from which the drug was purchased, (4) defendant did not manufacture dosages the size, shape or color of those ingested, etc.

[14]Assuming the *Sindell* decision can possibly be interpreted as an irrebuttable presumption, there is authority to support its constitutionality against procedural due process attack. The Court, in *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976) upheld the constitutionality of a federal statute making X-ray or clinical evidence of complicated pneumonociosis (black lung disease) a conclusive presumption of total disability and death due to said disease. The Court stated:

> "We cannot say that it would be irrational for Congress to conclude that impairment of health alone warrants compensation."

satisfy the standard of "rationality." The application of this standard in response to a due process attack upon rebuttable presumptions, allocations of the burden of proof and other evidentiary limitations has been comprehensively discussed by Justice Marshall, writing for the majority, in *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976).

Usery v. Turner Elkhorn Mining Co. involved a due process[15] challenge to certain evidentiary rules of a federal statute which provide a remedy to coal workers suffering from pneumonociosis (black lung disease). Under the statute, a coal mine operator is liable for death or total disability due to pneumonociosis contracted during employment in the operator's mine. Two coal mine operators challenged certain evidentiary rules designed to establish the element of causation. The provisions of the statute creating rebuttable presumptions of causation are summarized by the Court at 428 U.S. 11-12.

A comparison of the rebuttable presumptions in *Turner* with the *Sindell* rule reveals that the evidentiary rules[16] and

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[15]Due Process Clause of the Fifth Amendment to the U.S. Constitution.

[16]The major similarities between the *Turner* rebuttable presumptions and the rule of *Sindell* are as follows:

a. In *Turner*, the plaintiff coal miner or his survivors can shift the burden of proof for causation to the defendant coal mine operator by showing employment in the coal mines for a certain number of years. Under the rule of *Sindell*, a plaintiff DES daughter can shift the burden of proof for causation to the defendant drug companies by showing that she has joined in the action the manufacturers of a substantial share of the DES which her mother might have taken.

b. Like the defendants in *Turner*, the defendants in *Sindell* have the opportunity to introduce evidence to show the lack of causation.

c. The statute in *Turner* and the rule of *Sindell* both place a limitation on the type of evidence that a defendant can use to show lack of causation. The statute in *Turner* allows a plaintiff coal miner to use evidence of chest X-rays to trigger an irrebuttable presumption as to disability and death due to pneumonociosis (see 428 U.S. at 10-11), yet provides that none of the rebuttable presumptions in the statute can be defeated solely on the basis of such evidence, *e.g.*, the presumption that death was due to pneumonociosis (which is triggered by proof that a miner with 10 or more years' employment in the mines died from a "respirable disease") cannot be rebutted solely by evidence of

the due process issues[17] in both cases are very similar. Despite due process arguments almost identical to those advanced by Petitioners in *Sindell*, the *Turner* court upheld the constitutionality of all the evidentiary presumptions in the federal statute. The Court articulated the following standard for testing presumptions involving economic regulation of civil matters:

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a chest X-ray indicating the pneumonociosis was not the cause of death. 428 U.S. at 11-12. The *Sindell* decision allows a plaintiff DES daughter to use "market share" as evidence to trigger a shift in the burden of proof as to causation, yet does not allow a defendant drug manufacturer to show lack of causation solely on the basis of "market share" data.

d. Finally, both the statute in *Turner* and the rule of *Sindell* are cost-spreading devices which operate with less than perfect mathematical accuracy in individual cases. The statute in *Turner* could potentially hold a coal mine operator liable for pneumonociosis that was not contracted in his mines. Under the terms of the statute, a coal mine operator who cannot disprove causation can be held liable for death or disability benefits of a coal miner who contracted pneumonociosis while employed by a former employer or who never actually contracted pneumonociosis at all. Under the rule of *Sindell*, a defendant drug manufacturer who fails to show lack of causation can be held liable for a proportion of the judgment represented by its share of the DES market even though it may not have manufactured the particular DES that was ingested by the plaintiff's mother.

[17]The following are among the due process arguments that are common to the Petitioners in *Sindell* and the defendants in *Turner*:

a. The presumptions and limitations on rebuttal evidence constitutionally impair the defendant's ability to defend against the claims. 428 U.S. at 12.

b. The rules operate in an arbitrary and irrational manner by holding particular defendants liable for injuries they may not have actually caused. 428 U.S. at 18.

c. The rules will unfairly burden certain members of the industry. 428 U.S. at 18.

d. The rules create an improper method of cost-spreading. 428 U.S. at 19.

e. The facts triggering the operation of the presumptions are arbitrary (*i.e.*, in *Turner*, the 10 or 15 year period; in *Sindell*, a substantial proportion of the DES market). 428 U.S. at 29.

f. The evidentiary limitation denies defendants of due process because the evidence (i.e., in *Turner*, X-ray evidence; in *Sindell*, market share data) is frequently the sole evidence they can marshal to rebut the claim in question. 428 U.S. at 31.

> "That a legislative presumption of one fact from evidence of another may not constitute a denial of due process of law or a denial of the equal protection of the law it is only essential that there shall be some rational connection between the fact proved and the ultimate fact presumed, and that the inference of one fact from proof of another shall not be so unreasonable as to be a purely arbitrary mandate." 428 U.S. at 28.

In *Sindell*, the shifting of the burden of proof for causation is triggered by proof that the plaintiff has joined a "substantial" share of the manufacturers of the DES that her mother might have ingested. The issue is whether there is at least "some rational connection" between proof that a "substantial" share of the manufacturers have been joined and the presumption that one of the defendants so joined is actually responsible for plaintiff's injuries. In light of the Court's holding in *Turner*, the answer is clearly yes. A presumption that one of several defendants caused an injury (based upon proof that a "substantial share" of the possible defendants have been joined in the action) is not any more "arbitrary" or "irrational" than a presumption that a miner died due to pneumonociosis (based on proof that he worked in the mines for ten years and died of a "respirable disease").[18] In fact, the possibility of error under the *Sindell* rule is actually smaller than that under the statute in *Turner*. Because the defendants in *Sindell* are free to implead as many other manufacturers as they like, the possibility that one of the defendants before the court did not actually cause the plaintiff's injury can, virtually, be eliminated.

It is important to recognize that *Turner* does not require that the rules of law relating to causation match liability and actual responsibility for injury with mathematical accuracy. Responding to the argument that the retroactive application of the statute creates the possibility that a coal mine operator may be held liable for injuries that he did not actually cause, the Court stated:

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[18]In response to the coal mine operator's attack on proof of duration of employment as the basis of the presumption, the *Turner* court stated that as long as the durational requirement is not "purely arbitrary . . . no greater mathematical precision is required." 428 U.S. at 28.

> "We find, however, that the imposition of liability for effects and disabilities bred in the past is justified as a rational measure to spread the costs of the employees' disabilities to those who have profited from the fruits of their labor — the operators and the coal consumers . . ." 428 U.S. at 18.
>
> ". . . It is enough to say that the Act approaches the problem of cost-spreading rationally; whether a broader cost-spreading scheme would have been wiser or more practical under the circumstances is not a question of constitutional dimension. See e.g. *Ferguson v. Skrupa*, 372 U.S. at 730-732; *Williamson v. Lee Optical Co.*, 348 U.S. at 488." 428 U.S. at 18.

Under this principle, the *Sindell* decision's less than perfect mathematical allocation of liability is constitutionally permissible. Allocation of liability based upon market share is clearly a rational method of spreading costs among the manufacturers who profited from the sale of DES. As a result, the *Sindell* rule, like the statute in *Turner*, is a permissible method of compensating innocent victims of a dangerous instrumentality and allocating to the defendant "an actual, measurable cost of his business." See 428 U.S. at 19.

B. The Sindell Decision Does Not Deprive Petitioners of Substantive Due Process.

As previously stated, the *Sindell* decision shifts the burden of proof of causation to the defendants once the plaintiff DES daughter has shown that she was joined in the action a substantial share of the manufacturers of the DES that her mother might have ingested. Each defendant who fails to demonstrate that it could not have made the product which caused plaintiff's injuries is, then, held liable for the proportion of the judgment equal to its share of the DES market. Petitioners claim that this method of apportioning the judgment among the defendants who do not meet the burden of proof is "arbitrary and irrational" and, as a result, deprives them of substantive due process. This argument lacks merit.

(1) For Purposes of Due Process Review, the Sindell Decision Comes before the Court with a Presumption of Constitutionality.

The *Sindell* decision creates a rule of law affecting the economic and social welfare of the citizenry of California.

The rule was designed to provide a remedy for injuries suffered by innocent persons caused by a dangerous instrumentality and spread the costs of such injuries among the manufacturers who profited from its production.

It has long been established that a rule of law which adjusts the burdens and benefits of economic life for social welfare reasons comes before the Court with a presumption of constitutionality, and that the burden is on the one complaining to establish that the rule operates in an arbitrary and irrational manner. *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976); *Ferguson v. Skrupa*, 372 U.S. 726 (1963); *Williamson v. Lee Optical Co.*, 348 U.S. 483, 487-488 (1955); *United States v. Carolene Products Co.*, 304 U.S. 144, 148 (1938).

In the majority opinion in *Ferguson v. Skrupa*, Justice Black emphasized that the due process constitutionality of a rule of law regulating matters of economics and social welfare is not dependent on the Court's conception of the wisdom of the regulation. The Court's opinion states:

> "Legislative bodies have broad scope to experiment with economic problems, and this Court does not sit to subject the state to an intolerable supervision hostile to basic principles of our government and wholly beyond the protection which the general clause of the Fourteenth Amendment was intended to secure." 372 U.S. at 730.
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> ". . . We refuse to sit as a 'superlegislature to weigh the wisdom of legislation,' and we emphatically refuse to go back to the time when courts used the Due Process Clause 'to strike down state laws, regulatory of business and industrial conditions, because they may be unwise, improvident, or out of harmony with a particular school of thought.' " 372 U.S. at 731.

Finally, referring to a lawmaker's broad discretion in formulating rules which affect economic relationships and social welfare, Justice Powell, in his concurring opinion in *Usery v. Turner Elkhorn Mining Co.*, stated:

> "Nor does the Constitution require that legislation on economic matters be compatible with sound economics or even with normal fairness."

(2) The Sindell Decision Rests upon a Rational Basis.

The standard for testing the due process constitutionality of a rule of law regulating economic relationships and social welfare was specified in *United States v. Carolene Products Co.*, 304 U.S. 144 (1938). In that case, Justice Stone, writing for the majority, stated:

> "Regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in light of the *facts made known* and *generally assumed* it is of such a character as to preclude the assumption that it rests upon some *rational basis* within the knowledge and experience of the legislators." 304 U.S. at 152 [emphasis added].

In the *Sindell* opinion, the California Supreme Court made it very clear that it had a rational basis for apportioning the judgment in a DES case among defendants in proportion to their market share. After carefully considering the problem and analyzing each theory upon which Respondent requested relief, the California Supreme Court meticulously weighed the competing interests of the parties.[19]

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[19]In this weighing process, the Court considered the following interests:

a. The difficult problems created by a complex industrialized society, advances in science and technology which produce fungible goods which may harm innocent consumers and which cannot be traced to any specific producer. 26 Cal.3d at 610.

b. The inability of the consumer "to protect himself from serious, sometimes permanent, sometimes fatal injuries caused by deleterious drugs." 26 Cal.3d at 611.

c. The availability of evidence of causation. 26 Cal.3d at 611.

d. The ability of the parties to bear the cost of injury resulting from the manufacture of a defective product. 26 Cal.3d at 610-611.

e. The ability of the parties to discover, warn, guard against, and insure for risk of such injuries. 26 Cal.3d at 611.

f. The need to distribute the costs of such injuries to the manufacturer of the product and among the public as a cost of doing business. 26 Cal.3d at 611.

g. The possibility of holding a group of defendants liable for the injury, none of which was the actual manufacturer of the DES that the plaintiff's mother ingested. 26 Cal.3d at 611-612.

h. The possibility that each manufacturer's liability may not precisely conform to the injuries caused by its own products. 26 Cal.3d at 612-613.

i. The problems of determining market share with mathematical exactitude. 26 Cal.3d at 612-613.

j. The propriety of using market share as opposed to joint and several liability as a method of cost-spreading. 26 Cal.3d at 611.

After carefully weighing these interests, the Court decided that division of liability by market share was the best method of compensating the innocent victims of DES while fairly protecting the property interests of the defendant drug manufacturers. In making this decision, the California Supreme Court recognized that the facts before it made it *impossible* to create a rule that exactly matched liability with actual responsibility for injury. At the extremes, the Court was faced with either denying relief to DES daughters who cannot identify the manufacturer of the drug their mothers ingested or holding undiluted joint and several liability against the drug manufacturers. Refusing to accept either extreme, the California Supreme Court fashioned a rule of law that militates the inequities of both extremes. The Court adopted a rule of law apportioning damages in proportion to market share for those defendants who cannot demonstrate that they could not have caused plaintiff's injuries. Surely it is *not* irrational for a court to provide a remedy that protects the interests of both the plaintiff and the defendants in a tort case.

(3) When the Holding of Sindell Is Compared with the Holdings of Summers v. Tice, 33 Cal.2d 80 (1948) and Ybarra v. Spangard, 25 Cal.2d 486 (1944), Its Rationality Becomes Obvious.

Petitioners argue that the *Sindell* rule is "irrational and arbitrary" because it allows a court to hold them liable for injuries that their products did not actually cause. The error in this argument and the rationality of the *Sindell* court's method of apportioning damages becomes obvious when the potential for error under the *Sindell* rule is compared with the potential for error under the holdings of *Summers v. Tice* and *Ybarra v. Spangard*.

Petitioners do not question the constitutionality of *Summers v. Tice* or *Ybarra v. Spangard*. Both decisions have been part of California law for more than 30 years and have

been recognized by the Restatement of Torts[20] and almost every jurisdiction in the United States. Both cases hold independent tortfeasors jointly and severally liable for a plaintiff's injuries where neither the plaintiff nor the defendants can identify the particular tortfeasor who actually caused the plaintiff's injuries. Under the doctrines of both cases, there is potential for a 100% error in matching liability with actual responsibility for the harm (*i.e.*, a single innocent defendant can be held liable for 100% of the harm caused by another). For example, assume D1, D2, and D3 negligently shoot rifles in P's direction. Assume that P is severely injured by a single bullet from D3's gun but neither P, D1, D2, or D3 can prove that fact. Also assume D2 and D3 are judgment proof. Applying rule of *Summers v. Tice,* all three defendants are jointly and severally liable for P's injuries. Under the rule of joint and several liability, P may recover 100% of his damages from D1 thus creating a 100% error in matching liability with actual responsibility for harm.

Under the *Sindell* rule, the potential for error is much smaller. Under *Sindell,* the potential error with respect to a single innocent defendant is equal to his market share. For example, assume D1, D2 and D3 all negligently produced DES. Also assume respective market shares of 5%, 5% and

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[20]Restatement, Second, Torts §433B(3). It should be noted that the Restatement not only recognizes the doctrine of *Summers v. Tice* and *Ybarra v. Spangard* but also the need to make future modifications of this doctrine. Restatement, Second, Torts §433B(3) Comment 3(h) states:

> "It is possible that cases may arise in which some modification of the rule stated may be necessary because of complications arising from the fact that one of the actors involved is not or cannot be joined as a defendant, or because of the effect of lapse of time, or because of substantial differences in the character of the conduct of the actors or the risks which they have created. Since these cases have not arisen, and the situations which might arise are difficult to forecast, no attempt is made to deal with such problems in this section. The rule stated in Subsection (3) is not intended to preclude possible moderations if such situations call for it."

The California Supreme Court, in *Sindell,* modified the doctrine of *Summers v. Tice* and *Ybarra v. Spangard* in response to the precise circumstances anticipated by the Restatement above.

90%. Assume that the DES that P's mother ingested was produced by D3 but neither P, D1, D2 nor D3 can prove this fact. Applying the rule of *Sindell*, P, at most, could recover 5% of his damages from D1. The *Sindell* rule, therefore, reduces the matching error with respect to a single innocent defendant from 100% to a percentage equal to the market share of that defendant.

Keeping in mind that Petitioners have not challenged the constitutionality of either *Summers v. Tice* or *Ybarra v. Spangard* and that the *Sindell* method of allocating liability actually reduces the potential for error created by the well-established doctrine of these two cases, Petitioners' substantive due process arguments are not persuasive.

III.

THE SINDELL DECISION DOES NOT DENY PETITIONERS EQUAL PROTECTION OF THE LAWS.

The Fourteenth Amendment provides that "No state shall . . . deny to any person within its jurisdiction the equal protections of the laws."

A. For Purposes of Equal Protection Review, the Sindell Decision Comes before the Court with a Presumption of Constitutionality.

As discussed in Section II B (1) above, the *Sindell* decision is a rule of law affecting the economic and social welfare of the citizenry of California. The standards for reviewing rules affecting matters of economics and social welfare under the Equal Protection Clause are similar to the standards for reviewing such rules under the Due Process Clause. The major difference is that the Equal Protection review tests the rationality of the "classifications" drawn by the rule of law.

This Court, in *City of New Orleans v. Duke's*, 427 U.S. 297 (1976), stated:

> "When local economic regulation is challenged solely as violating the Equal Protection Clause, this Court consistently defers to legislative determinations as to the desirability of particular statutory discriminations. See, *e.g., Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356 (1973). Unless a classification trammels fundamental personal rights or is drawn upon

> inherently suspect distinctions such as race, religion, or alienage, *our decisions presume the constitutionality* of the statutory discriminations and require only that the classification challenged be rationally related to a legitimate state interest. States are accorded wide latitude in the regulation of their local economies under their police powers, and rational distinctions may be made with substantially less than mathematical exactitude.
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> . . . In short, the judiciary may not sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines, See, *e. g., Day-Brite Lighting, Inc. v. Missouri,* 342 U.S. 421, 423 (1952); in the local economic sphere, it is only the invidious discrimination, the wholly arbitrary act, which cannot stand consistently with the Fourteenth Amendment. See, *e. g., Ferguson v. Skrupa,* 372 U.S. 726, 732 (1963)." 427 U.S. at 303-304. [emphasis added].

B. The Classifications Drawn by the Sindell Decision Are Rationally Related to a Legitimate State Interest.

Petitioners argue that the *Sindell* rule treats them differently than defendants in other tort cases.[21] As shown below, the difference in treatment is "rationally related to a legitimate state interest."

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[21]Upjohn argues that the *Sindell* rule discriminates against petitioners on the basis of wealth. Upjohn bases its argument on the following portion of the California Supreme Court's opinion in *Sindell*:

> "From a broader policy standpoint, defendants are better able to bear the cost of injury resulting from the manufacture of a defective product." 26 Cal.3d at 611.

The California Supreme Court's intent in making this statement is clear. The statement merely considers one of the factors that courts have used for decades to decide tort cases — which party (plaintiff or defendant) can best bear the cost of the injury. This consideration cannot possibly be construed to indicate the intent to create a discriminatory classification among similarly situated defendants. At most, it treats the plaintiff and defendants differently. But because plaintiff and defendants are obviously not parties who are "similarly situated," a rule treating them differently does not raise an actionable Equal Protection issue.

It is undisputable that a state has a legitimate interest in compensating its citizens for injuries caused by dangerous products. The *Sindell* rule accommodates this interest by shifting the burden of proof for causation to the defendants once the plaintiff has shown that she has joined in the action a substantial share of the manufacturers of the DES that her mother might have taken. Why should such defendants be treated differently than defendants in other tort cases? The answer is simple. The rules are different because the circumstances of a DES daughter's injuries are different than the circumstances of the injuries in most tort cases.

Ms. Sindell was injured by a drug manufacturer, one of possibly 200 drug manufacturers, which she cannot identify because the product that caused her injuries was fungible and did not produce discoverable damage to her until almost twenty years after its purchase and ingestion by her mother.

The California Supreme Court was faced with the difficult choice between denying compensation to plaintiffs like Ms. Sindell or fashioning a new rule of law which adapts to the unusual circumstances of their injuries. The California Supreme Court chose the latter alternative and fashioned a remedy which shifts the burden of proof and apportions damages on the basis of "market share."[22] Because the

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[22]Upjohn argues that a rule based on "market share" and "substantial share" is so unworkable and uneven that certain defendants are deprived of Equal Protection of the Laws. The California Supreme Court effectively rebuts this argument by stating:

> "But just as a jury cannot be expected to determine the precise relationship between fault and liability in applying the doctrine of comparative fault (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804) or partial indemnity (*American Motorcycle Assn. v. Superior Court*,(1978) 20 Cal.3d 578), the difficulty of apportioning damages among the defendant producers in exact relation to their market share does not seriously militate against the rule we adopt. As we said in *Summers* with regard to the liability of independent tortfeasors, where a correct division of liability cannot be made 'the trier of fact may make it the best it can.' (33 Cal.2d at p. 88)."

The California Supreme Court's position is supported by the following passage of the majority opinion of *City of New Orleans v. Duke's*, 427 U.S. 297, 303 (1976):

> "States are accorded wide latitude in the regulation of their local economics under their police powers, and rational distinctions may be made with *substantially less* than mathematical exactitude." [emphasis added].

circumstances of Ms. Sindell's injuries prevented her from identifying the particular tortfeasor who actually caused her harm, the California Supreme Court had no choice but to depart from the rules generally used in tort cases to establish the element of causation. Such departures are not uncommon to California law. As stated earlier, the California Supreme Court made exactly the same policy judgment in *Summers v. Tice* and *Ybarra v. Spangard*. Like the decisions in *Summers* and *Ybarra*, the decision in *Sindell* was made after carefully weighing the interests of the State, the plaintiff and the defendants. See discussion of Section II B (2), *supra*. The *Sindell* rule was drawn so carefully that it creates a potential for error (with respect to a single innocent defendant) which is actually smaller than that created by either *Summers* or *Ybarra*. See discussion in Section II B (3), *supra*. Because the *Sindell* rule reduces the potential for error and addresses the same circumstances as the well-established doctrine of *Summers* and *Ybarra*, an Equal Protection challenge to *Sindell* can, necessarily, be no more persuasive than an Equal Protection challenge to *Summers* and *Ybarra*.

IV.

THE SINDELL DECISION IS NOT INVALID UNDER THE SUPREMACY CLAUSE.

Article VI, Clause 2 (the "Supremacy Clause") provides that the "Constitution and the laws of the United States which shall be made in pursuance thereof; and all Treaties made or which shall be made under the authority of the United States shall be the supreme law of the land . . ." Thus to the extent that Congress has exercised one of its powers, any inconsistent state law is prohibited.

In the recent United States Supreme Court decision in *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978), this Court drew from prior decisions, *e.g.*, *Jones v. Rath Packaging Co.*, 430 U.S. 519, 525 (1977) and *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218 (1947) and enunciated five areas for inquiry for determining whether Congress intended to foreclose state legislation in a particular area. 435 U.S. at 157. That Court noted that the Congressional purpose to supersede the police power of the states

". . . may be evidenced in several ways. [1] The scheme of federal regulation may be so persuasive as to make reasonable the inference that Congress left no room for the States to supplement it . . . [2] Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject . . . [3] Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose . . . [4] Even if Congress has not completely foreclosed state legislation in a particular area, a state statute is void to the extent that it actually conflicts with a valid federal statute. A conflict will be found where compliance with both federal and state regulations is a physical impossibility . . . or [5] where the state 'law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . .' " 435 U.S. at 158 [citations omitted; numbers added for emphasis].

A. The Scheme of Drug Regulation Is Not so Persuasive as to Make Reasonable the Inference That Congress Left No Room for the State to Supplement It.

Although the introduction of new drugs is extensively regulated by the Federal government, a long line of United States Supreme Court cases have held that Congress has left room for state and municipal regulations. In *Corn Products Refining Company v. Eddy*, 249 U.S. 427 (1919), this Court upheld a state statute that supplemented the Federal Drug and Cosmetic Act.[23] Furthermore, numerous cases have recognized state civil remedies where personal injury, death or property damage result to consumers from dangerous

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[23]The most recent decision of this Court on this matter upheld the right of a state to supplement the registration scheme of the Federal Drug and Cosmetic Act. *Whalen v. Roe*, 429 U.S. 589 (1977).

drugs.[24] See, *e.g.*, *State of Florida Ex Rel., Broward County v. Eli Lilly Co.*, 329 F. Supp. 364, 365 (1971) and cases cited therein. The federal scheme of drug regulation is simply not so persuasive to infer that the state may not supplement it with a rule of civil liability such as *Sindell*.

B. The Federal Interest in Regulating Drugs Is Not so Dominant That the Federal System Should Be Assumed to Preclude Enforcement of State Laws on the Same Subject.

An act of Congress can demonstrate a federal interest so dominant that it precludes any state regulation of the same subject matter. In *Hines v. Davidowitz*, 312 U.S. 52 (1941), this Court found that a federal statute requiring the registration of aliens evidenced such an interest. After recognizing that the federal interest in regulating foreign affairs is constitutionally paramount, the Court in *Hines* invalidated a Pennsylvania alien registration law. The Court noted:

> "The Supremacy of the national power in the general field of foreign affairs, including power over immigration, naturalization and deportation is made clear by the Constitution." 312 U.S. at 62.

There is no similar federal interest that precludes the remedy provided by the *Sindell* rule. Unlike the area of alienage and naturalization, rules governing tort liability for defective products have been traditionally considered within the province of state governments.

C. The Rule in the Sindell Case Does Not Purport to Govern the Same Area and Does Not Impose an Obligation Similar to Those Imposed by the Federal Drug and Cosmetic Act.

A clear and manifest purpose of Congress to supersede the police power of a state may be shown by "the object

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[24]The legislative history of the Federal Food and Drug Act indicates that an express provision for a private right of action for damages was included in an early version of the bill but was omitted from all later versions after being attacked on the ground that it would create an unnecessary federal action *duplicative* of state remedies. *State of Florida Ex Rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364, 365, n. 2 (1971) citing Hearings on S 1944, before a Subcommittee of the on Commerce, U.S. Senate, 73d Cong., 2d Sess., pp. 10, 144, 219, 403, 431, 444 (1933).

sought to be obtained by the federal government and the character of obligations imposed on it may reveal the same purpose." *Southern R. Co. v. Railroad Commission,* 236 U.S. 439 (1915); *Charleston & W.C.R. Co. v. Varnville,* 237 U.S. 597 (1915). In the above cases, this Court struck down state statutes that purported "to prescribe additional regulation and what they may deem auxiliary provisions for the *same purpose.*" *Southern R. Co.,* 236 U.S. at 447 [emphasis added].

The *Sindell* rule is not an attempt to achieve the same purposes as the Federal Drug and Cosmetic Act, nor does it impose the same obligations as that Act. The Federal Drug and Cosmetic Act is concerned with the safety and efficacy of prescription drugs. The Act achieves this purpose through labeling, registration and disclosure requirements. The Act makes no attempt to define or prescribe a drug manufacturer's liability for injuries caused by defective products. *Orthopedic Equipment v. Eutsler,* 276 F.2d 455 (1960).

In contrast, the *Sindell* decision is merely a mechanism designed to equitably allocate responsibility for damage caused by a drug manufacturer's defective products. Its only purpose is to compensate innocent DES victims who cannot identify the manufacturer of the products that caused them harm.

Because the Federal Drug and Cosmetic Act does not purport to govern rules of civil liability arising from defective drugs and the *Sindell* decision does not purport to govern labeling, registration or disclosure requirements for drugs, the *Sindell* rule is not preempted because it attempts to govern the same area or impose the same obligations as an existing federal law.

D. The Sindell Decision Is Not in Direct Conflict with a Valid Federal Statute.

In the instant case, Petitioners made no claim (nor could they make such a claim) that the *Sindell* decision is in direct conflict with any federal authority; that is, that "any federal enactment is directly contradictory on [its] face . . . so that compliance with both is a literal impossibility." Tribe, American Constitutional Law, (1978 Ed.) §6-24, p. 377, 378.

E. The Sindell Decision Does Not Stand as an Obstacle to the Accomplishment and Execution of the Full Purposes and Objectives of Congress.

Petitioners contend that the *Sindell* decision must be set aside as a violation of the Supremacy Clause because it will frustrate the policies and objectives of the federal drug regulatory system. In support of this contention, Petitioners argue that *Sindell* is a chamber of horrors. They argue that the *Sindell* rule will create serious anti-competitive effects, tend to create and prolong monopoly and discourage the production of generic drugs. These arguments are not persuasive for a number of reasons.

Before proceeding further, it is interesting to note the unusual nature of Petitioners' arguments. Nowhere in Petitioners' arguments before the Supreme Court or in their petitions for a writ of certiorari have they denied (or even implied that they deny) that their products have caused thousands and perhaps millions of innocent women like Ms. Sindell serious bodily injury. Yet, Petitioners argue that a rule that imposes liability on them for these injuries is unfair because it may adversely affect their profitability. It is difficult to understand why it is "unfair" to make a person or an entity responsible for the consequences of its own actions.

(1) Anti-Competitive Effects.[25]

Petitioners' argument that the *Sindell* rule will adversely affect price competition among drug manufacturers is, at best, tenuous. Logically, it is difficult to understand how the *Sindell* rule will have any serious adverse effect on price competition. Because the rule apportions liability on the basis of market share, the production costs of small firms should be no more adversely affected than those of large firms. If anything, the California Supreme Court appears to have chosen a method of apportioning liability which minimizes the effects on price competition.

Petitioners also argue that the *Sindell* rule will drive small manufacturers out of business and create barriers to entry into the drug manufacturing industry. This argument suffers

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[25]Petition of Rexall Drug Company and Eli Lilly and Company at at p. 21.

from a fatal flaw: the objective of the federal regulatory system is *not* to protect manufacturers of *defective* products. The purpose of the Food, Drug and Cosmetic Act, 21 USC, §301, *et seq.*, is to protect consumers, who in the circumstances of modern industrialism are largely beyond self-protection. *62 Cases of Jam v. United States*, 340 U.S. 593 (1951). The *Sindell* rule does not impose liability on all manufacturers in the drug industry regardless of fault. It imposes liability *only* when a manufacturer has produced a defective product. If the *Sindell* rule forces anyone out of business, it will be manufacturers who produce too many defective products. If anything, the elimination or exclusion of such manufacturers will further, rather than frustrate, Congress' objective to protect helpless consumers.

Even assuming certain anti-competitive effects are created, the *Sindell* rule would not automatically be invalid under the Supremacy Clause as contrary to federal policies favoring competition. In the recent case of *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117 (1978), this Court addressed appellant Exxon's claim that certain anti-competitive effects of a Maryland statute violated the Supremacy Clause. Rejecting this argument, this Court stated:

> "We are, therefore, satisfied that . . . the broad implications of the Sherman Act cannot be fairly construed as a congressional decision to preempt the power of Maryland to enact this law. For if an adverse effect on competition were in and of itself enough to render a state statute invalid, the state's power to engage in economic regulation would be effectively destroyed." 437 U.S. at 132.

(2) Monopolistic Effects.

Petitioners' argument that the *Sindell* rule will tend to create and prolong monopoly[26] suffers from the same flaw as their argument that it will drive small manufacturers out of business and create barriers to entry. As stated above, there is nothing inherently evil about eliminating or excluding manufacturers of defective products from the drug industry. The purpose of federal drug regulations is to protect consumers of drug products, not manufacturers.

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[26]Petition of Upjohn at p. 27.

Petitioners cite *Sears Roebuck Co. v. Stiffel*, 376 U.S. 225 (1964) as authority for their monopoly argument. It should be noted that their reliance on this case for the proposition that they assert is both unpersuasive and unjustified. The issue in the *Sears* case was whether the state's unfair competition law was compatible with federal patent law where a mechanical device that was not entitled to a patent was the subject matter of an unfair competition action. This Court found that the statute was incompatible with the federal law because the application of the state's unfair competition law to the patent area "would . . . permit the state to block off from the public something that the federal law has said belongs to the public . . ." 376 U.S. at 231, 232. This case clearly does not apply to *Sindell*. The *Sears* case would apply only if there were a federal statute regulating when a person may or may not sue a drug company. There is, of course, no such statute.

(3) Effect on Production and Marketing of Generic Drugs.

From a logical point of view, Petitioners' argument — that the *Sindell* rule will frustrate federal policies favoring the production and marketing of generic drugs[27] — is no more persuasive than their arguments cited in Sections (1) and (2) above. As stated before, the rule of *Sindell* does not assign liability without fault. To be responsible for damages under this rule, a drug manufacturer *must* produce a defective product. Contrary to Petitioners' arguments, such a rule will more likely serve to further, rather than frustrate, Congress' objective to protect helpless consumers. Holding drug manufacturers liable for the injuries caused by their products will definitely provide incentives to produce safer drugs.

As authority for their argument that *Sindell* interferes with federal policies favoring the production and marketing of generic drugs, Petitioners cite certain statements contained in a Department of Health, Education and Welfare bulletin and made at hearings before the Subcommittee of the Committee on Labor and Public Welfare.[28] Petitioners argue that

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[27]Petition of Rexall Drug Company and Eli Lilly and Company at pp. 22, 23.

[28]Petition of Rexall Drug Company and Eli Lilly and Company at pp. 22, 23.

these statements constitute a "clear and manifest"[29] statement by Congress that no state rule, regulation or statute may burden (however indirectly) the production of generic drugs. The statements cited by Petitioners are clearly not sufficient to manifest such intent. Traditionally, courts have required a more definitive statement manifesting the congressional intent to preclude state involvement in a particular area. *Pharmaceutical Soc., State of N.Y., Inc. v. Lefkowitz*, 454 F. Supp. 1175, 1179 (1978); *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Furthermore, the objectives of Congress are generally not frustrated by the imposition of liability for harm arising out of congressionally favored activities.[30] That is, of course, unless Congress has specifically exempted an activity from liability. *Sherlock, et al. v. Alling, Administrator*, 93 U.S. 99 (1876).

V.

THE SINDELL DECISION IS NOT A REGULATION AFFECTING INTERSTATE COMMERCE.

Article I, Section 8, Clause 3, of the United States Constitution provides: "[The Congress shall have the power] . . . To regulate Commerce . . . among the several States." This language has been interpreted to limit the States' ability to regulate interstate commerce.

Petitioners claim that the *Sindell* decision contravenes the Commerce Clause by creating an impermissible burden on interstate commerce. However, it is well-established that civil remedies — which only "indirectly" relate to or affect interstate commerce — are not "regulations" for purposes of the Commerce Clause.

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[29]Consideration of this claim begins with the recognition that the "historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Ray v. Atlantic Richfield Co.*, 435 U.S. at 157.

[30]There are many products and activities that are favored by Congress or by some department of the executive branch. Yet, manufacturers of these products and participants in these activities remain liable for the harm they cause. The defense industry is one such example. Certainly, Congress is interested in the production of the greatest number of weapons at the lowest cost. Just as certain, however, is the idea that the manufacturers of those weapons are liable for damages negligently caused during the production of those weapons.

The constitutionality of civil remedies under the Commerce Clause was thoroughly treated by this Court in *Missouri, Kansas & Texas v. Haber*, 169 U.S. 613 (1898), and in *Sherlock, et al. v. Alling, Administrator*, 93 U.S. 99 (1876). *Haber* involved a Kansas statute that made any shipper or importer of diseased cattle liable for all damages caused by those cattle. Under the terms of the statute, a prima facie case of liability was established upon proof that the allegedly diseased cattle were shipped into Kansas through an area below the thirty-seventh parallel. This presumption could be rebutted by demonstrating that the cattle had been kept in an area west of the twenty-second meridian or north of the thirty-fourth parallel.

The *Sherlock* case involved an action for damages under an Indiana statute giving a right of action in favor of the personal representative of one whose death was caused by the wrongful act or omission of another.

In both cases, defendants claimed that the state statutes were impermissible burdens on interstate commerce. The *Haber* and *Sherlock* courts rejected this argument after concluding that the statutes did not constitute a regulation within the meaning of the Commerce Clause. The *Sherlock* court concluded:

> "Legislation in a great variety of ways may affect commerce and persons engaged without constituting a regulation of it within the meaning of the Constitution." 93 U.S. at 103.

The Court justified this conclusion by stating:

> "The Indiana statute imposes no tax, proscribes no duty and in no respect interferes with any regulation for the navigation and use of vehicles. It only declares a general principle respecting the *liability* of all persons within the jurisdiction of the State *for torts* resulting in the death of parties injured. General legislation of those prescribing the liabilities or duties of citizens of a state without distinction as to pursuit or calling is not open to any valid objection because it may affect persons engaged in foreign or interstate commerce." 93 U.S. at 103 [emphasis added].

Citing the *Sherlock* decision, the *Haber* court stated:

> "It is said that the statute of Kansas giving a right of action for damages is, in itself a regulation of commerce among the States, and therefore, inconsistent with the power of Congress to regulate such commerce. But that statute is not within the meaning of the Constitution, nor in any just sense, a regulation of commerce among the states . . . It did nothing more than declare as a *rule of civil liability* in Kansas, that anyone driving, shipping or transporting or causing to be driven, shipped or transported, into or through any county, in that state, cattle liable to impart or capable of communicating Texas, splenic or Spanish fever to domestic cattle should be responsible to any person injured thereby." 169 U.S. at 625. [emphasis added].

In light of the similarities between *Haber* and *Sherlock* and *Sindell*,[31] it is clear that *Sindell* cannot be considered a regulation affecting interstate commerce. The *Sindell* decision does not prohibit any commerce among the states. It does nothing more than make drug manufacturers responsible for damage caused by a dangerous product. It simply fashions a rule of civil liability well within the state's inherent power to protect its citizenry. Moreover, the *Sindell* decision imposes no tax, proscribes no duty, and in no respect interferes with any regulations providing for the manufacture and distribution of drugs. For these reasons, the rule in the *Sindell* decision is not prohibited by Article I, Section 8, Clause 3 of the Constitution.

Because the *Sindell* rule is not a regulation affecting interstate commerce, it is unnecessary to address whether this decision is rationally related to a legitimate state end, whether the regulatory burden imposed on interstate commerce is outweighed by the state's interest, or whether there is a less burdensome alternative to the remedy chosen by the California Supreme Court.[32]

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[31]There are four important similarities between the rule of law in the *Sindell* case and statutes of *Haber* and *Sherlock*: (a) All create or allow causes of actions for negligent behavior; (b) all involve use of rebuttable presumptions; (c) all were challenged on commerce clause grounds; (d) all did not directly affect interstate commerce.

[32]Even if these issues were relevant, the discussion in Section III B clearly demonstrates that the *Sindell* rule is rationally related to a legitimate state goal, and that the California Supreme Court arrived at this decision after exhaustively weighing all relevant factors.

CONCLUSION.

For the reasons stated above, Respondent respectfully requests that Petitioners' Petitions for a Writ of Certiorari to the Supreme Court of California be denied.

Respectfully submitted,

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APPENDIX A.

The California Supreme Court Summarized the allegations in Respondent's complaint as follows:

"Between 1941 and 1971, defendants were engaged in the business of manufacturing, promoting and marketing diethylstilbesterol (DES), a drug which is a synthetic compound of the female hormone estrogen. The drug was administered to plaintiff's mother and the mothers of the class she represents[1] for the purpose of preventing miscarriage. In 1947, the Food and Drug Administration authorized the marketing of DES as a miscarriage preventative, but only on an experimental basis, with a requirement that the drug contain a warning label to that effect.

DES may cause cancerous vaginal and cervical growths in the daughters exposed to it before birth, because their mothers took the drug during pregnancy. The form of cancer from which these daughters suffer is known as adenocarcinoma, and it manifests itself after a minimum latent period of 10 or 12 years. It is a fast-spreading and deadly disease, and radical surgery is required to prevent it from spreading. DES also causes adenosis, precancerous vaginal and cervical growths which may spread to other areas of the body. The treatment for adenosis is cauterization, surgery, or cryosurgery. Women who suffer from this condition must be monitored by biopsy or colposcopic examination twice a year, a painful and expensive procedure. Thousands of women whose mothers received DES during pregnancy are unaware of the effects of the drug.

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[1]The plaintiff class alleged consists of "girls and women who are residents of California and who have been exposed to DES before birth and who may or may not know that fact or the dangers" to which they were exposed. Defendants are also sued as representatives of a class of drug manufacturers which sold DES after 1941.

In 1971, the Food and Drug Administration ordered defendants to cease marketing and promoting DES for the purpose of preventing miscarriages, and to warn physicians and the public that the drug should not be used by pregnant women because of the danger to their unborn children.

During the period defendants marketed DES, they knew or should have known that it was a carcinogenic substance, that there was a grave danger after varying periods of latency it would cause cancerous and precancerous growths in the daughters of the mothers who took it, and that it was ineffective to prevent miscarriage. Nevertheless, defendants continued to advertise and market the drug as a miscarriage preventative. They failed to test DES for efficacy and safety; the tests performed by others, upon which they relied, indicated that it was not safe or effective. In violation of the authorization of the Food and Drug Administration, defendants marketed DES on an unlimited basis rather than as an experimental drug, and they failed to warn us of its potential danger.[2]

Because of defendants' advertised assurances that DES was safe and effective to prevent miscarriage, plaintiff was exposed to the drug prior to her birth. She became aware of the danger from such exposure within one year of the time she filed her complaint. As a result of the DES ingested by her mother, plaintiff developed a malignant bladder tumor which was removed by surgery. She suffers from adenosis and must constantly be monitored by biopsy or colposcopy to insure early warning of further malignancy.

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[2]It is alleged also that defendants failed to determine if there was any means to avoid or treat the effects of DES upon the daughters of women exposed to it during pregnancy, and failed to monitor the carcinogenic effects of the drug.

The first cause of action alleges that defendants were jointly and individually negligent in that they manufactured, marketed and promoted DES as a safe and efficacious drug to prevent miscarriage, without adequate testing or warning, and without monitoring or reporting its effects.

A separate cause of action alleges that defendants are jointly liable regardless of which particular brand of DES was ingested by plaintiff's mother because defendants collaborated in marketing, promotion and testing the drug, relied upon each other's tests, and adhered to an industry-wide safety standard. DES was produced from a common and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product; defendants knew or should have known that it was customary for doctors to prescribe the drug by its generic rather than its brand name and that pharmacists filled prescriptions from whatever brand of the drug happened to be in stock.

Other causes of action are based upon theories of strict liability, violation of express and implied warranties, false and fraudulent representations, misbranding of drugs in violation of federal law, conspiracy and "lack of consent."

Each cause of action alleges that defendants are jointly liable because they acted in concert, on the basis of express and implied agreements, and in reliance upon and ratification and exploitation of each other's testing and marketing methods.

Plaintiff seeks compensatory damages of $1 million and punitive damages of $10 million for herself. For the members of her class, she prays for equitable relief in the form of an order that defendants warn physicians and others of the danger of DES and the necessity of performing certain tests to determine the presence of diseases caused by the

drug, and that they establish free clinics in California to perform such tests.

Defendants demurred to the complaint. While the complaint did not expressly allege that plaintiff could not identify the manufacturer of the precise drug ingested by her mother, she stated in her points and authorities in opposition to the demurrers filed by some of the defendants that she was unable to make the identification, and the trial court sustained the demurrers of these defendants without leave to amend on the ground that plaintiff did not and stated she could not identify which defendant had manufactured the drug responsible for her injuries. Thereupon, the court dismissed the action.[3] This appeal involves only five of ten defendants named in the complaint.[4]

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[3]There are minor variations in the procedures employed as to the various defendants. Thus, for example, Eli Lilly and Company filed a motion for summary judgment, or alternatively judgment on the pleadings, rather than a demurrer; the court treated the motion as a demurrer.

The demurrer of Abbott Laboratories, the first defendant to file a demurrer and the first to secure a dismissal, was sustained with leave to amend on the ground that plaintiff had failed to allege that a product manufactured by Abbott had caused her injuries (as opposed to the reason given by the trial court for sustaining the demurrers of the other defendants that plaintiff expressly stated that she could not identify a particular manufacturer). Upon plaintiff's failure to amend the complaint, the action was dismissed as to Abbott. A few days after the dismissal, plaintiff stated in a brief in opposition to the demurrers filed by defendants other than Abbott that she could not make the identification.

Abbott asserts that as to it the issue we consider on the appeal is not properly raised because plaintiff's statement that she could not identify the manufacturer was not made until after the action had been dismissed as to Abbott. This contention is without merit. Plaintiff's failure to amend her complaint after Abbott's demurrer was sustained with leave to amend was based upon her inability to identify a specific manufacturer. Clearly, Abbott interpreted the complaint in this fashion, for it moved for dismissal on the ground that the complaint alleges that plaintiff "does not know the identity of the drug . . . ingested" by her mother. Thus, Abbott may not now claim that the complaint is insufficient to raise the issues involved in this appeal.

The trial court did not determine other issues raised by the complaint, such as whether the case was properly brought by a class action.

[4]Abbott Laboratories, Eli Lilly and Company, E.R. Squibb and Sons, The Upjohn Company, and Rexall Drug Company are respondents. The action was dismissed or the appeal abandoned on various grounds as to other defendants named in the complaint; *e.g.*, one defendant demonstrated it had not manufactured DES during the period plaintiff's mother took the drug.

Plaintiff Maureen Rogers filed a complaint containing allegations generally similar to those made by Sindell. She seeks compensatory and punitive damages on her own behalf, and on behalf of a class described in substantially the same terms as in Sindell's complaint, as well as equitable relief comparable to that sought by Sindell. The trial court sustained demurrers of E. R. Squibb & Sons, the Upjohn Company, and Rexall Drug Company.[5] Subsequent to the dismissal of her action against these defendants, Rogers amended the complaint to allege that Eli Lilly and Company, one of the defendants named in her complaint, has manufactured the drug used by her mother. Although Sindell's action and the present case have been consolidated on appeal, much of the discussion which follows will apply to Rogers only if she does not succeed in establishing that Eli Lilly and Company manufactured the DES taken by her mother. "Plaintiff" as used in this opinion refers to Sindell, and we discuss only the allegations of Sindell's complaint.

This case is but one of a number filed throughout the country seeking to hold drug manufacturers liable for injuries allegedly resulting from DES prescribed to the plaintiffs' mothers since 1947.[6] According to a note in the Fordham Law Review, estimates of the number of women who took the drug during pregnancy ranged from 1½ million to 3 million. Hundreds, perhaps thousands, of the daughters of these women suffer from adenocarcinoma, and the incidence of vaginal adenosis among them is 30 to 90 percent. (Comment, *DES and a Proposed Theory of Enterprise Li-*

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[5]While the trial court did not specify the ground upon which the demurrers were sustained, the points and authorities filed by the parties emphasized the failure of Rogers to identify a particular manufacturer as the source of her injuries, and we may assume for the purpose of this appeal that this was the basis of the court's order.

[6]DES was marketed under many different trade names.

ability (1978) 46 Fordham L. Rev. 963, 964-967 [hereafter Fordham Comment].) Most of the cases are still pending. With two exceptions,[7] those that have been decided resulted in judgments in favor of the drug company defendants because of the failure of the plaintiffs to identify the manufacturer of the DES prescribed to their mothers.[8] The same result was reached in a recent California case. (*McCreery v. Eli Lilly & Co.* (1978) 87 Cal. App. 3d 77, 82-84.) The present action is another attempt to overcome this obstacle to recovery." 26 Cal. 3d at 595-597.

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[7]In a recent New York case a jury found in the plaintiff's favor in spite of her inability to identify a specific manufacturer of DES. An appeal is pending. (*Bichler v. Eli Lilly and Co.* (Sup. Ct. N.Y. 1979).) A Michigan appellate court recently held that plaintiffs had stated a cause of action against several manufacturers of DES even though identification could not be made. (Abel v. Eli Lilly and Co. (decided Dec. 5, 1979) Docket No. 60497.) That decision is on appeal to the Supreme Court of Michigan.

[8]*E.g., Gray v. United States* (S.D. Texas 1978) 445 F.Supp. 337. In their briefs, defendants refer to a number of other cases in which trial courts have dismissed actions in DES cases on the ground stated above.